

Risk Assessment Model -- Calculation of Potential Risks from Consumption of Human Milk

Subject ID	PCB 153 Conc in Fish Cf (ug/kg)	PCB 153 Slope Factor SFo (ug/kg/day)-1	PCB 153 Intermediate MRL (ug/kg/day)	PCB 153 Chronic RID (ug/kg/day)	PCB 153 Half-life h (days)	PCB 153 Mother ADDm (ug/kg/day)	PCB 153 Milk Cmf (ug/kg-lipid)	PCB 153 Fraction of human milk that is fat	PCB 153 Infant ADDca-I (ug/kg/day)	PCB 153 Infant ADDnc-I (ug/kg/day)	Infant/Mother Exposure Ratio	Excess Lifetime Cancer Risk Mother ELCRm	Infant ELCRi	Infant/Mother Risk Ratio	Hazard Quotient Mother HQm	Infant HQI	Infant/Mother Risk Ratio
6-Month																	
210	0.002	0.03	0.02	10038	0.0337	733	0.04	0.04509	3.16	94	2.9E-05	9.0E-05	3.1	1.7	105	62	
93	0.002	0.03	0.02	10038	0.0154	334	0.04	0.02052	1.44	94	1.3E-05	4.1E-05	3.1	0.77	48	62	
222	0.002	0.03	0.02	10038	0.0088	192	0.04	0.01182	0.83	94	7.6E-06	2.4E-05	3.1	0.44	28	62	
199	0.002	0.03	0.02	10038	0.0075	163	0.04	0.01002	0.70	94	6.4E-06	2.0E-05	3.1	0.38	23	62	
55	0.002	0.03	0.02	10038	0.0064	139	0.04	0.00856	0.60	94	5.5E-06	1.7E-05	3.1	0.32	20	62	
159	0.002	0.03	0.02	10038	0.0057	124	0.04	0.00762	0.53	94	4.9E-06	1.5E-05	3.1	0.29	18	62	
265	0.002	0.03	0.02	10038	0.0039	84	0.04	0.00517	0.36	94	3.3E-06	1.0E-05	3.1	0.19	12	62	
236	0.002	0.03	0.02	10038	0.0015	33	0.04	0.00201	0.14	94	1.3E-06	4.0E-06	3.1	0.08	5	62	

Conc in Fish Cf (mg/kg)	Slope Factor SFo (mg/kg/day)-1	Intermediate MRL (mg/kg/day)	Chronic RID (mg/kg/day)	Half-life h (days)	Mother ADDm (mg/kg/day)	Milk Cmf (mg/kg-lipid)	Fraction of human milk that is fat	Infant ADDca-I (mg/kg/day)	Infant ADDnc-I (mg/kg/day)	Infant/Mother Exposure Ratio	Excess Lifetime Cancer Risk Mother ELCRm	Infant ELCRi	Infant/Mother Risk Ratio	Hazard Quotient Mother HQm	Infant HQI	Infant/Mother Risk Ratio	
Total PCBs (1 year)	1	2	0.00003	0.00002	2555	0.000273	3.02	0.04	0.00011	0.00735	27	2.3E-04	2.1E-04	0.90	14	245	18
Total PCBs (0.5 yr)	1	2	0.00003	0.00002	2555	0.000273	3.02	0.04	0.00019	0.01304	48	2.3E-04	3.7E-04	1.59	14	435	32
PCB 153 (0.5 yr)	1	2	0.00003	0.00002	1387	0.000273	1.64	0.04	0.00010	0.0071	26	2.3E-04	2.0E-04	0.88	14	236	17
PCB 153 (0.5 yr)	1	2	0.00003	0.00002	1387	0.000273	1.64	0.08	0.00020	0.0142	52	2.3E-04	4.1E-04	1.73	14	473	35
PCB 153 (0.5 yr)	1	2	0.00003	0.00002	10038	0.000273	5.94	0.04	0.00037	0.0256	94	2.3E-04	7.3E-04	3.1	14	853	62
PCB 153 (0.5 yr)	1	2	0.00003	0.00002	10038	0.000273	5.94	0.08	0.00073	0.0512	187	2.3E-04	1.5E-03	6.2	14	1705	125
PCB 153 (1 year)	1	2	0.00003	0.00002	1387	0.000273	1.64	0.04	0.00006	0.0040	15	2.3E-04	1.1E-04	0.49	14	134	10
PCB 153 (1 year)	1	2	0.00003	0.00002	10038	0.000273	5.94	0.04	0.00021	0.0144	52	2.3E-04	4.1E-04	1.7	14	478	35

Notes:

Acceptable levels are ELCR = 1E-6 and HQ = 1

Equations

$$\text{ADDm} = (\text{Cf} \times \text{Irf} \times \text{Conv} \times \text{Ff} \times \text{BWm}^{\text{h}}) / (\text{Fone} \times \text{Ftwo} \times \text{IRMad} / \text{Sto} \times 30 / 70)$$

$$\text{ADDca-I} = (\text{Cmf} \times \text{IRMad} \times \text{Irf} \times \text{Conv} \times \text{Ff} \times \text{BWm}^{\text{h}}) / (\text{Fone} \times \text{Ftwo} \times \text{IRMad} / \text{Sto})$$

$$\text{ELCRm} = \text{ADDm} / (\text{RID} \times 30)$$

$$\text{ELCRi} = \text{ADDca-I} / \text{RID}$$

Default Values

Cf	chemical specific	mg/kg	Concentration of chemical in fish
Irf		17.5 g/day	Mother's ingestion rate of fish
Conv		0.001 kg/g	Conversion factor
Ff		1 fraction	Fraction of fish contaminated
BWm		64 kg	Body weight of mother
h	chemical specific	days	Half-life of chemical in body
Fone		0.9 fraction	Fraction of ingested chemical stored in fat
Ftwo		0.3 fraction	Fraction of mother's weight that is fat
IRMad		0.149 kg/kg/day	Infant's ingestion rate of milk (averaged over exposure duration)
Fthree		0.04 fraction	Fraction of human milk that is fat
Ffour		0.9 fraction	Fraction of ingested chemical that is absorbed
Ffive		0.543 fraction	Average fraction of initial chem conc present during infant exposure duration
Edi		1 year	Exposure duration of breast-feeding infant
Efi		365 days/year	Exposure frequency of breast-feeding infant
Atc		25550 days	Averaging time - carcinogens (70 years)
Sfo	chemical specific	(mg/kg/day)-1	Slope Factor - oral
RID	chemical specific	mg/kg/day	Reference Dose - oral
Conv2		1.00E-06 kg/mg	Conversion factor 2

Calculated Values

ADDm	mg/kg/day	Average Daily Dose to mother
Cmf	mg/kg-lipid	Chemical concentration in milkfat
ADDca-I	mg/kg/day	Average Daily Dose to breast-feeding infant, cancer
ADDnc-I	mg/kg/day	Average Daily Dose to breast-feeding infant, non-cancer
ELCRm	risk	Excess Lifetime Cancer Risk to mother
ELCRi	risk	Excess Lifetime Cancer Risk to infant
HQm	quotient	Hazard Quotient to mother
HQi	quotient	Hazard Quotient to infant

Calculation of F5 (see Attachment 2 to Appendix C of draft DEQ Human Health Risk Assessment Guidance)

k	calculated	(days)-1	rate constant for chemical loss in body = $\ln(2)/h$
b		0.9 kg/day	daily secretion of milk
c	calculated	fraction	fraction of chemical lost in human milk per day
hb	calculated	days	maternal half-life for breastfeeding
kb	calculated	(days)-1	rate constant for chemical loss by breastfeeding = $\ln(2)/hb$
b'0		150 ml/kg/day	mean milk intake rate 0 to 3 months
b'91		140 ml/kg/day	mean milk intake rate 3 to 6 months
b'183		110 ml/kg/day	mean milk intake rate 6 to 9 months
		85 ml/kg/day	mean milk intake rate 9 to 12 months
		145 ml/kg/day	mean milk intake rate 0 to 6 months
		121 ml/kg/day	mean milk intake rate 0 to 12 months
		1.03 g/ml	density of milk
		149 g/kg/day	mean milk intake rate 0 to 6 months
		0.149 kg/kg/day	mean milk intake rate 0 to 6 months
		124 g/kg/day	mean milk intake rate 0 to 12 months
		0.124 kg/kg/day	mean milk intake rate 0 to 12 months

Half-life h (days)	k	kb	b'91	b'183	Six months of exposure f5	One year f5	Maternal Breastfeeding Halflife hb (days)	
1387	0.000500	0.00219	0.861	0.746	0.933	0.733	0.803	0.547
2555	0.000271	0.00196	0.859	0.740	0.933	0.733	0.802	0.543
10038	0.000069	0.00176	0.858	0.736	0.933	0.733	0.801	0.540

approximately 1 year

Table 1
Comparison of PCB-153 Concentrations in Milk Calculated from EPA Model, Haddad Model, and Yang Model

Subject ID	PCB 153 Half-life (days)	Dose to Mother ADDm (ug/kg/day)	EPA Initial Milk Concentration (ug/kg-lipid)			6-Month Average Milk Concentration (ug/kg-lipid)			6-Month Concentration Ratios			1-Year Average Milk Concentration (ug/kg-lipid)			1-Year Concentration Ratios		
						EPA	Haddad	Yang	EPA	EPA	Haddad	EPA	Haddad	Yang	EPA	EPA	Haddad
			Haddad	Yang	Yang	Haddad	Yang	Yang	Haddad	Yang	Yang	Haddad	Yang	Yang	Haddad	Yang	Yang
210	10,038	0.0337	733	629	463	428	1.36	1.47	1.08	539	456	318	1.18	1.70	1.43		
93	10,038	0.0154	334	286	153	194	1.88	1.47	0.79	246	135	144	1.82	1.70	0.94		
222	10,038	0.0088	192	165	137	109	1.20	1.52	1.26	141	135	78	1.05	1.82	1.73		
199	10,038	0.0075	163	140	79	94	1.78	1.49	0.84	120	72	70	1.66	1.72	1.03		
55	10,038	0.0064	139	119	98	82	1.22	1.46	1.20	102	89	61	1.15	1.68	1.47		
159	10,038	0.0057	124	106	53	74	1.99	1.45	0.73	91	50	55	1.84	1.67	0.91		
265	10,038	0.0039	84	72	50	51	1.45	1.40	0.97	62	48	38	1.29	1.62	1.26		
236	10,038	0.0015	33	28	14	19	2.00	1.47	0.74	24	13	14	1.87	1.69	0.90		
Mean:			0.0104	Mean:	193	131	131		1.61	1.47	*	166	125	97	1.48	1.70	*
				Min:	28	14	19					24	13	14			
				1st Quart	98	52	68					84	49	50			
				Median	130	88	88					111	81	65			
				3rd Quart	195	141	130					167	135	94			
				Max	629	463	428					539	456	318			

Notes:

10,038 days = 27.5 years

Dose to Mother from Haddad simulations9 28 09.xls

Initial milk concentration assumes 27.5 year half-life, so steady state is not reached in mother

Average EPA milk concentration over 6 months = initial conc x Cmilkfat91/Cmilkfat0

Average EPA milk concentration over 6 months = initial conc x Cmilkfat183/Cmilkfat0

Haddad 6-month and 1-year averages from Haddad simulations9 28 09.xls

Yang 6-month and 1-year values (not averages) from report_for_oregon_request.xls

* A mean of ratios above and below 1 is not meaningful

Table 2
Comparison of PCB-153 Doses to Infant Calculated from EPA Model, Haddad Model, and Yang Model

Subject ID	PCB 153 Half-life (days)	Dose to Mother ADDm (ug/kg/day)	EPA Initial Milk Concentration (ug/kg-lipid)			6-Month Average Dose to Infant (ug/kg-BW/Day)			6-Month Dose Ratios			1-Year Average Dose to Infant (ug/kg-BW/Day)			1-Year Dose Ratios		
						EPA	Haddad	Yang	EPA	EPA	Haddad	EPA	Haddad	Yang	EPA	EPA	Haddad
			Haddad	Yang	Yang	Haddad	Yang	Yang	Haddad	Yang	Yang	Haddad	Yang	Yang	Haddad	Yang	Yang
210	10,038	0.0337	733	3.16	2.110	1.84	1.50	1.71	1.15	2.13	1.709	0.92	1.24	2.31	1.85		
93	10,038	0.0154	334	1.44	0.699	0.84	2.06	1.72	0.84	0.97	0.522	0.42	1.85	2.31	1.25		
222	10,038	0.0088	192	0.83	0.627	0.47	1.32	1.77	1.34	0.56	0.506	0.23	1.10	2.47	2.24		
199	10,038	0.0075	163	0.70	0.359	0.40	1.95	1.73	0.89	0.47	0.276	0.20	1.71	2.33	1.36		
55	10,038	0.0064	139	0.60	0.448	0.35	1.34	1.70	1.27	0.40	0.342	0.18	1.18	2.29	1.94		
159	10,038	0.0057	124	0.53	0.244	0.32	2.19	1.69	0.77	0.36	0.189	0.16	1.90	2.27	1.19		
265	10,038	0.0039	84	0.36	0.227	0.22	1.59	1.64	1.03	0.24	0.181	0.11	1.35	2.21	1.63		
236	10,038	0.0015	33	0.14	0.064	0.08	2.19	1.71	0.78	0.09	0.049	0.04	1.93	2.30	1.19		
Mean:			0.0104	Mean:	0.97	0.60	0.57		1.77	1.71	*	0.65	0.47	0.28	1.53	2.31	*
				Min:	0	0	0					0	0	0			
				1st Quart	0	0	0					0	0	0			
				Median	1	0	0					0	0	0			
				3rd Quart	1	1	1					1	1	0			
				Max	3	2	2					2	2	1			

Notes:

10,038 days = 27.5 years

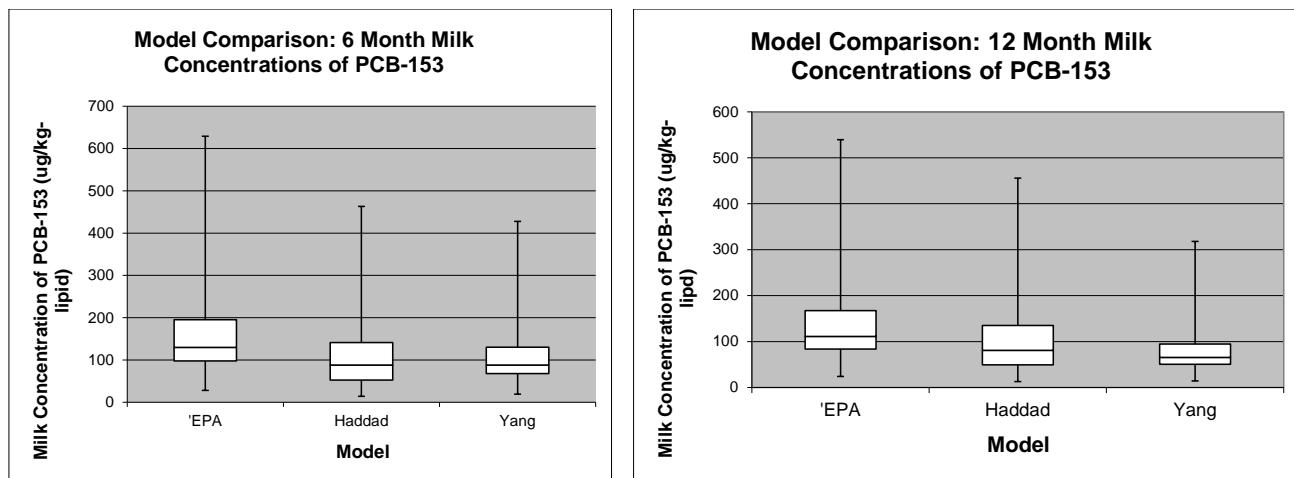
Dose to Mother from Haddad simulations9 28 09.xls

Initial milk concentration assumes 27.5 year half-life, so steady state is not reached in mother

Haddad 6-month and 1-year averages from Haddad simulations9 28 09.xls

Yang 6-month and 1-year values calculated from final (not initial) concentration (from report_for_oregon_request.xls) times EPA model factors for ADDnc-i

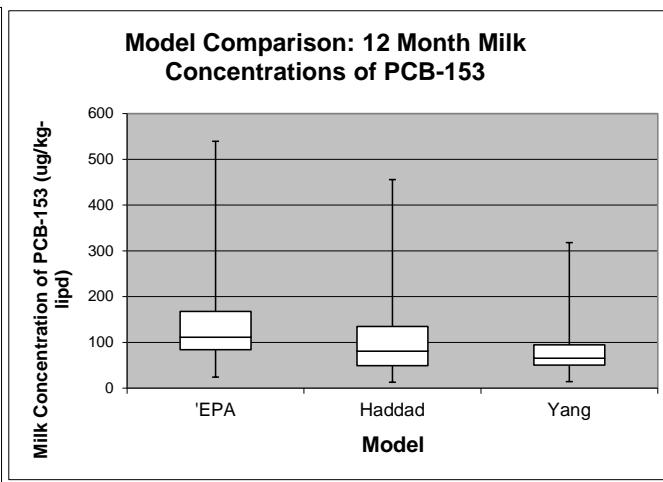
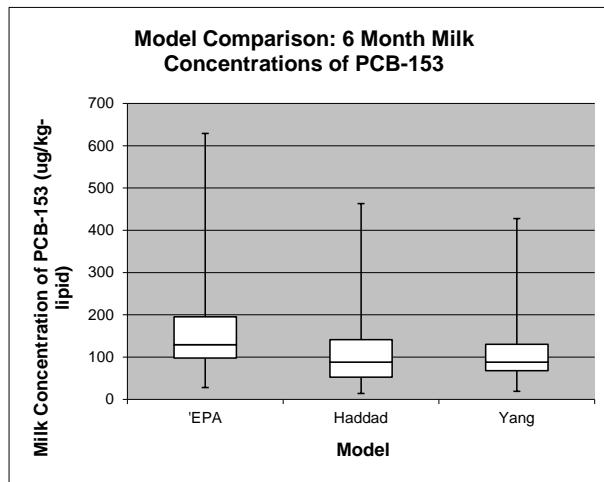
* A mean of ratios above and below 1 is not meaningful



	Month Average Milk Concentration			Year Average Milk Concentration		
	'EPA	Haddad	Yang	'EPA	Haddad	Yang
(ug/kg-lipid)	(ug/kg-lipid)	(ug/kg-lipid)	(ug/kg-lipid)	(ug/kg-lipid)	(ug/kg-lipid)	(ug/kg-lipid)
Max	629.0237	463.1089	427.7	539.4604	455.7518	318
3rd Quart	195.2383	141.1597	130.15	167.4393	134.8293	94.45
Median	129.6338	88.21578	87.95	111.1759	80.79489	65.4
1st Quart	97.78026	52.40885	67.975	83.85786	49.13619	50.475
Min:	28.0427	14.04099	19.1	24.04985	12.84823	14.2

Max	433.7855	321.9492	297.55	372.0211	320.9224	223.55
3rd Quart	65.60447	52.94395	42.2	56.2634	54.03445	29.05
Median	31.85353	35.80694	19.975	27.31808	31.65871	14.925
1st Quart	97.78026	52.40885	67.975	83.85786	49.13619	50.475
Min:	69.73757	38.36785	48.875	59.80801	36.28795	36.275

This section is to trick Excel into making the above data into box and whisker plots



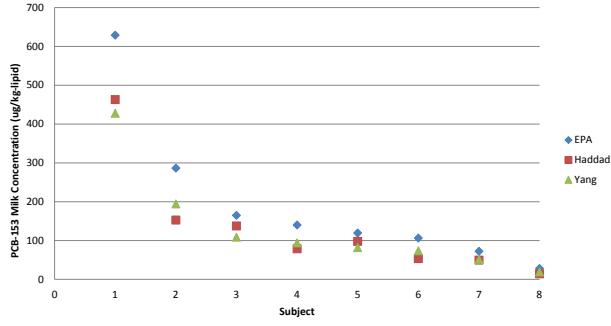
6-Month Average Milk Concentration (ug/kg-lipid) (ug/kg-lipid) (ug/kg-lipid)

	EPA	Haddad	Yang
1	629.0237	463.1089	427.7
2	286.2808	152.5954	194.2
3	164.8907	137.3478	108.8
4	139.7955	78.55625	94
5	119.4721	97.87531	81.9
6	106.3216	53.31956	73.5
7	72.15619	49.67671	51.4
8	28.0427	14.04099	19.1

1-Year Average Milk Concentration (ug/kg-lipid) (ug/kg-lipid) (ug/kg-lipid)

	EPA	Haddad	Yang
1	539.4604	455.7518	318
2	245.5189	135.2194	144.4
3	141.4128	134.6933	77.8
4	119.8908	72.25095	69.9
5	102.4611	89.33884	60.9
6	91.18306	49.54191	54.6
7	61.88226	47.91901	38.1
8	24.04985	12.84823	14.2

Model Comparison
6-Month PCB-153 Milk Concentrations



Model Comparison
1-Year PCB-153 Milk Concentrations

